

GEN Docket 98-68

AGREEMENT ON MUTUAL RECOGNITION
BETWEEN
THE EUROPEAN COMMUNITY
AND THE UNITED STATES OF AMERICA

DOCKET FILE COPY ORIGINAL

RECEIVED

JUN 15 1998

FEDERAL COMMUNICATIONS COMMISSION
OFFICE OF THE SECRETARY

No. of Copies rec'd 2
List A B C D E

CE/USA/en 1

TABLE OF CONTENTS

	Page
1. Framework	CE/USA/en 4
2. Telecommunication Equipment	CE/USA/Annex/en 1
3. Electromagnetic Compatibility (EMC)	CE/USA/Annex/en 17
4. Electrical Safety	CE/USA/Annex/en 32
5. Recreational Craft	CE/USA/ANNEX/en 42
6. Pharmaceutical Good Manufacturing Practices (GMPs)	CE/USA/Annex/en 51
7. Medical Devices	CE/USA/Annex/en 79-143

The EUROPEAN COMMUNITY, and the GOVERNMENT OF THE UNITED STATES OF AMERICA, hereinafter referred to as "the Parties",

CONSIDERING the traditional links of friendship that exist between the United States of America (U.S.) and the European Community (EC);

DESIRING to facilitate bilateral trade between them;

RECOGNIZING that mutual recognition of conformity assessment activities is an important means of enhancing market access between the Parties;

RECOGNIZING that an agreement providing for mutual recognition of conformity assessment activities is of particular interest to small and medium-sized businesses in the U.S. and the EC;

RECOGNIZING that any such mutual recognition also requires confidence in the continued reliability of the other Party's conformity assessments;

RECOGNIZING the importance of maintaining each Party's high levels of health, safety, environmental and consumer protection;

RECOGNIZING that mutual recognition agreements can positively contribute in encouraging greater international harmonization of standards;

NOTING that this Agreement is not intended to displace private sector bilateral and multilateral arrangements among conformity assessment bodies or to affect regulatory regimes allowing for manufacturers' self-assessments and declarations of conformity.

BEARING IN MIND that the Agreement on Technical Barriers to Trade, an agreement annexed to the Agreement establishing the World Trade Organization (WTO), imposes obligations on the Parties as Contracting Parties to the WTO, and encourages such Contracting Parties to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment;

RECOGNIZING that any such mutual recognition needs to offer an assurance of conformity with applicable technical regulations or standards equivalent to the assurance offered by the Party's own procedures;

RECOGNIZING the need to conclude an Agreement on Mutual Recognition (MRA) in the field of conformity assessment with sectoral annexes; and

BEARING in mind the respective commitments of the Parties under bilateral, regional and multilateral environment, health, safety and consumer protection agreements.

HAVE AGREED AS FOLLOWS:

ARTICLE 1

DEFINITIONS

1. The following terms and definitions shall apply to this Agreement only:
 - Designating Authority means a body with power to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies as specified under this Agreement.
 - Designation means the identification by a Designating Authority of a conformity assessment body to perform conformity assessment procedures under this Agreement.
 - Regulatory Authority means a government agency or entity that exercises a legal right to control the use or sale of products within a Party's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.
2. Other terms concerning conformity assessment used in this Agreement shall have the meaning given elsewhere in this Agreement or in the definitions contained in Guide 2 (1996 edition) of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). In the event of an inconsistency between ISO/IEC Guide 2 and definitions in this Agreement, the definitions in this Agreement shall prevail.

ARTICLE 2

PURPOSE OF THE AGREEMENT

This Agreement specifies the conditions by which each Party will accept or recognize results of conformity assessment procedures, produced by the other Party's conformity assessment bodies or authorities, in assessing conformity to the importing Party's requirements, as specified on a sector-specific basis in the Sectoral Annexes, and to provide for other related cooperative activities. The objective of such mutual recognition is to provide effective market access throughout the territories of the Parties with regard to conformity assessment for all products covered under this Agreement. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the Party alleging its market access has been denied, may, within 90 days of such consultation, invoke its right to terminate the Agreement in accordance with Article 21.

ARTICLE 3

GENERAL OBLIGATIONS

1. The United States shall, as specified in the Sectoral Annexes, accept or recognize results of specified procedures, used in assessing conformity to specified legislative,

regulatory, and administrative provisions of the United States, produced by the other Party's conformity assessment bodies and/or authorities.

2. The European Community and its Member States shall, as specified in the Sectoral Annexes, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory and administrative provisions of the European Community and its Member States, produced by the other Party's conformity assessment bodies and/or authorities.

3. Where sectoral transition arrangements have been specified in Sectoral Annexes, the above obligations will apply following the successful completion of those sectoral transition arrangements, with the understanding that the conformity assessment procedures utilized assure conformity to the satisfaction of the receiving Party, with applicable legislative, regulatory and administrative provisions of that Party, equivalent to the assurance offered by the receiving Party's own procedures.

ARTICLE 4

GENERAL COVERAGE OF THE AGREEMENT

1. This Agreement applies to conformity assessment procedures for products and/or processes and to other related cooperative activities as described in this Agreement.

2. Sectoral Annexes may include:

- (a) a description of the relevant legislative, regulatory and administrative provisions pertaining to the conformity assessment procedures and technical regulations;
- (b) a statement on the product scope and coverage;
- (c) a list of Designating Authorities;
- (d) a list of agreed conformity assessment bodies or authorities or a source from which to obtain a list of such bodies or authorities and a statement of the scope of the conformity assessment procedures for which each has been agreed;
- (e) the procedures and criteria for designating the conformity assessment bodies;
- (f) a description of the mutual recognition obligations;
- (g) a sectoral transition arrangement;
- (h) the identity of a sectoral contact point in each Party's territory; and
- (i) a statement regarding the establishment of a Joint Sectoral Committee.

3. This Agreement shall not be construed to entail mutual acceptance of standards or technical regulations of the Parties and, unless otherwise specified in a Sectoral Annex, shall not entail the mutual recognition of the equivalence of standards or technical regulations.

ARTICLE 5

TRANSITIONAL ARRANGEMENTS

The Parties agree to implement the transitional commitments on confidence building as specified in the Sectoral Annexes.

1. The Parties agree that each sectoral transitional arrangement shall specify a time period for completion.
2. The Parties may amend any transitional arrangement by mutual agreement.
3. Passage from the transitional phase to the operational phase shall proceed as specified in each Sectoral Annex, unless either Party documents that the conditions provided in such Sectoral Annex for a successful transition are not met.

ARTICLE 6

DESIGNATING AUTHORITIES

The Parties shall ensure that the Designating Authorities specified in the Sectoral Annexes have the power and competence in their respective territories to carry out decisions under this Agreement to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies.

ARTICLE 7

DESIGNATION AND LISTING PROCEDURES

The following procedures shall apply with regard to the designation of conformity assessment bodies and the inclusion of such bodies in the list of conformity assessment bodies in a Sectoral Annex:

- (a) The Designating Authority identified in a Sectoral Annex shall designate conformity assessment bodies in accordance with the procedures and criteria set forth in that Sectoral Annex;
- (b) A Party proposing to add a conformity assessment body to the list of such bodies in a Sectoral Annex shall forward its proposal of one or more designated conformity assessment bodies in writing to the other Party with a view to a decision by the Joint Committee;
- (c) Within 60 days following receipt of the proposal, the other Party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the inclusion in the Sectoral Annex of the proposed conformity assessment body or bodies shall take effect; and

- (d) In the event that the other Party contests on the basis of documented evidence the technical competence or compliance of a proposed conformity assessment body, or indicates in writing that it requires an additional 30 days to more fully verify such evidence, such conformity assessment body shall not be included on the list of conformity assessment bodies in the applicable Sectoral Annex. In this instance, the Joint Committee may decide that the body concerned be verified. After the completion of such verification, the proposal to list the conformity assessment body in the Sectoral Annex may be resubmitted to the other Party.

ARTICLE 8

SUSPENSION OF LISTED CONFORMITY ASSESSMENT BODIES

The following procedures shall apply with regard to the suspension of a conformity assessment body listed in a Sectoral Annex:

- (a) A Party shall notify the other Party of its contestation of the technical competence or compliance of a conformity assessment body listed in a Sectoral Annex and the contesting Party's intent to suspend such conformity assessment body. Such contestation shall be exercised when justified in an objective and reasoned manner in writing to the other Party;
- (b) The conformity assessment body shall be given prompt notice by the other Party and an opportunity to present information in order to refute the contestation or to correct the deficiencies which form the basis of the contestation;
- (c) Any such contestation shall be discussed between the Parties in the relevant Joint Sectoral Committee. If there is no Joint Sectoral Committee, the contesting Party shall refer the matter directly to the Joint Committee. If agreement to suspend is reached by the Joint Sectoral Committee or, if there is no Joint Sectoral Committee, by the Joint Committee, the conformity assessment body shall be suspended;
- (d) Where the Joint Sectoral Committee or Joint Committee decides that verification of technical competence or compliance is required, it shall normally be carried out in a timely manner by the Party in whose territory the body in question is located, but may be carried out jointly by the Parties in justified cases;
- (e) If the matter has not been resolved by the Joint Sectoral Committee within 10 days of the notice of contestation, the matter shall be referred to the Joint Committee for a decision. If there is no Joint Sectoral Committee, the matter shall be referred directly to the Joint Committee. If no decision is reached by the Joint Committee within 10 days of the referral to it, the conformity assessment body shall be suspended upon the request of the contesting Party;
- (f) Upon the suspension of a conformity assessment body listed in a Sectoral Annex, a Party is no longer obligated to accept or recognize the results of conformity assessment procedures performed by that conformity assessment body subsequent to suspension. A Party shall continue to accept the results of conformity assessment procedures performed by that conformity assessment body prior to suspension, unless a Regulatory Authority of the Party decides otherwise based on

health, safety or environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex; and

- (g) The suspension shall remain in effect until agreement has been reached by the Parties upon the future status of that body.

ARTICLE 9

WITHDRAWAL OF LISTED CONFORMITY ASSESSMENT BODIES

The following procedures shall apply with regard to the withdrawal from a Sectoral Annex of a conformity assessment body:

- (a) A Party proposing to withdraw a conformity assessment body listed in a Sectoral Annex shall forward its proposal in writing to the other Party;
- (b) Such conformity assessment body shall be promptly notified by the other Party and shall be provided a period of at least 30 days from receipt to provide information in order to refute or to correct the deficiencies which form the basis of the proposed withdrawal;
- (c) Within 60 days following receipt of the proposal, the other Party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the withdrawal from the list in the Sectoral Annex of the conformity assessment body shall take effect;
- (d) In the event the other Party opposes the proposal to withdraw by supporting the technical competence and compliance of the conformity assessment body, the conformity assessment body shall not at that time be withdrawn from the list of conformity assessment bodies in the applicable Sectoral Annex. In this instance, the Joint Sectoral Committee or the Joint Committee may decide to carry out a joint verification of the body concerned. After the completion of such verification, the proposal for withdrawal of the conformity assessment body may be resubmitted to the other Party; and
- (e) Subsequent to the withdrawal of a conformity assessment body listed in a Sectoral Annex, a Party shall continue to accept the results of conformity assessment procedures performed by that conformity assessment body prior to withdrawal, unless a Regulatory Authority of the Party decides otherwise based on health, safety and environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex.

ARTICLE 10

MONITORING OF CONFORMITY ASSESSMENT BODIES

The following shall apply with regard to the monitoring of conformity assessment bodies listed in a Sectoral Annex:

- (a) Designating Authorities shall assure that their conformity assessment bodies listed in a Sectoral Annex are capable and remain capable of properly assessing conformity of products or processes, as applicable, and as covered in the applicable Sectoral Annex. In this regard, Designating Authorities shall maintain, or cause to maintain, ongoing surveillance over their conformity assessment bodies by means of regular audit or assessment;
- (b) The Parties undertake to compare methods used to verify that the conformity assessment bodies listed in the Sectoral Annexes comply with the relevant requirements of the Sectoral Annexes. Existing systems for the evaluation of conformity assessment bodies may be used as part of such comparison procedures;
- (c) Designating Authorities shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures. With the consent of both Parties, this consultation may include joint participation in audits/inspections related to conformity assessment activities or other assessments of conformity assessment bodies listed in a Sectoral Annex; and
- (d) Designating Authorities shall consult, as necessary, with the relevant Regulatory Authorities of the other Party to ensure that all technical requirements are identified and are satisfactorily addressed.

ARTICLE 11

CONFORMITY ASSESSMENT BODIES

Each Party recognizes that the conformity assessment bodies listed in the Sectoral Annexes fulfil the conditions of eligibility to assess conformity in relation to its requirements as specified in the Sectoral Annexes. The Parties shall specify the scope of the conformity assessment procedures for which such bodies are listed.

ARTICLE 12

EXCHANGE OF INFORMATION

1. The Parties shall exchange information concerning the implementation of the legislative, regulatory, and administrative provisions identified in the Sectoral Annexes.
2. Each Party shall notify the other Party of legislative, regulatory and administrative changes related to the subject matter of this Agreement at least 60 days before their entry into force. Where considerations of safety, health or environmental protection require more urgent action, a Party shall notify the other Party as soon as practicable.
3. Each Party shall promptly notify the other Party of any changes to its Designating Authorities and/or conformity assessment bodies.
4. The Parties shall exchange information concerning the procedures used to ensure that the listed conformity assessment bodies under their responsibility comply with the legislative, regulatory, and administrative provisions outlined in the Sectoral Annexes.

5. Regulatory Authorities identified in the Sectoral Annexes shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures and to ensure that all technical requirements are identified and are satisfactorily addressed.

ARTICLE 13

SECTORAL CONTACT POINTS

Each Party shall appoint and confirm in writing contact points to be responsible for activities under each Sectoral Annex.

ARTICLE 14

JOINT COMMITTEE OF THE PARTIES

1. The Parties hereby establish a Joint Committee consisting of representatives of each Party. The Joint Committee shall be responsible for the effective functioning of the Agreement.
2. The Joint Committee may establish Joint Sectoral Committees comprised of appropriate Regulatory Authorities and others deemed necessary.
3. Each Party shall have one vote in the Joint Committee. The Joint Committee shall make its decisions by unanimous consent. The Joint Committee shall determine its own rules and procedures.
4. The Joint Committee may consider any matter relating to the effective functioning of this Agreement. In particular it shall be responsible for:
 - (a) listing, suspension, withdrawal and verification of conformity assessment bodies in accordance with this Agreement;
 - (b) amending transitional arrangements in Sectoral Annexes;
 - (c) resolving any questions relating to the application of this Agreement and its Sectoral Annexes not otherwise resolved in the respective Joint Sectoral Committees;
 - (d) providing a forum for discussion of issues that may arise concerning the implementation of this Agreement;
 - (e) considering ways to enhance the operation of this Agreement;
 - (f) coordinating the negotiation of additional Sectoral Annexes; and
 - (g) considering whether to amend this Agreement or its Sectoral Annexes in accordance with Article 21.

5. When a Party introduces new or additional conformity assessment procedures affecting a Sectoral Annex, the Parties shall discuss the matter in the Joint Committee with a view to bringing such new or additional procedures within the scope of this Agreement and the relevant Sectoral Annex.

ARTICLE 15

PRESERVATION OF REGULATORY AUTHORITY

1. Nothing in this Agreement shall be construed to limit the authority of a Party to determine, through its legislative, regulatory and administrative measures, the level of protection it considers appropriate for safety; for protection of human, animal, or plant life or health; for the environment; for consumers; and otherwise with regard to risks within the scope of the applicable Sectoral Annex.

2. Nothing in this Agreement shall be construed to limit the authority of a Regulatory Authority to take all appropriate and immediate measures whenever it ascertains that a product may: (a) compromise the health or safety of persons in its territory; (b) not meet the legislative, regulatory, or administrative provisions within the scope of the applicable Sectoral Annex; or (c) otherwise fail to satisfy a requirement within the scope of the applicable Sectoral Annex. Such measures may include withdrawing the products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, and preventing the recurrence of such problems, including through a prohibition on imports. If the Regulatory Authority takes such action, it shall inform its counterpart authority and the other Party within fifteen days of taking such action, providing its reasons.

ARTICLE 16

SUSPENSION OF RECOGNITION OBLIGATIONS

Either Party may suspend its obligations under a particular Sectoral Annex, in whole or in part, if:

- (a) a Party suffers a loss of market access for the Party's products within the scope of the Sectoral Annex as a result of the failure of the other Party to fulfil its obligations under the Agreement;
- (b) the adoption of new or additional conformity assessment requirements as referenced in Article 14(5) results in a loss of market access for the Party's products within the scope of the Sectoral Annex because conformity assessment bodies designated by the Party in order to meet such requirements have not been recognized by the Party implementing the requirements; or
- (c) the other Party fails to maintain legal and regulatory authorities capable of implementing the provisions of this Agreement.

ARTICLE 17

CONFIDENTIALITY

1. Each Party agrees to maintain, to the extent required under its laws, the confidentiality of information exchanged under this Agreement.
2. In particular, neither Party shall disclose to the public, nor permit a conformity assessment body to disclose to the public, information exchanged under this Agreement that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation.
3. A Party or a conformity assessment body may, upon exchanging information with the other Party or with a conformity assessment body of the other Party, designate the portions of the information that it considers to be exempt from disclosure.
4. Each Party shall take all precautions reasonably necessary to protect information exchanged under this Agreement from unauthorized disclosure.

ARTICLE 18

FEES

Each Party shall endeavor to ensure that fees imposed for services under this Agreement shall be commensurate with the services provided. Each Party shall ensure that, for the sectors and conformity assessment procedures covered under this Agreement, it shall charge no fees with respect to conformity assessment services provided by the other Party.

ARTICLE 19

AGREEMENTS WITH OTHER COUNTRIES

Except where there is written agreement between the Parties, obligations contained in mutual recognition agreements concluded by either Party with a party not a signatory to this Agreement (a third party) shall have no force and effect with regard to the other Party in terms of acceptance of the results of conformity assessment procedures in the third party.

ARTICLE 20

TERRITORIAL APPLICATION

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied, and under the conditions laid down in that Treaty and, on the other hand, to the territory of the United States.

ARTICLE 21

ENTRY INTO FORCE, AMENDMENT AND TERMINATION

1. This Agreement including its Sectoral Annexes on Telecommunication Equipment, Electromagnetic Compatibility, Electrical Safety, Recreational Craft, Pharmaceutical Good Manufacturing Practices (GMPs), and Medical Devices shall enter into force on the first day of the second month following the date on which the Parties have exchanged letters confirming the completion of their respective procedures for the entry into force of this Agreement.
2. This Agreement including any Sectoral Annex may, through the Joint Committee, be amended in writing by the Parties. The Parties may add a Sectoral Annex upon the exchange of letters. Such Annex shall enter into force 30 days following the date on which the Parties have exchanged letters confirming the completion of their respective procedures for the entry into force of the Sectoral Annex.
3. Either Party may terminate this Agreement in its entirety or any individual Sectoral Annex thereof by giving the other Party six months notice in writing. In the case of termination of one or more Sectoral Annexes, the Parties will seek to achieve by consensus to amend this Agreement, with a view to preserving the remaining Sectoral Annexes, in accordance with the procedures in this Article. Failing such consensus, the Agreement shall terminate at the end of six months from the date of notice.
4. Following termination of the Agreement in its entirety or any individual Sectoral Annex thereof, a Party shall continue to accept the results of conformity assessment procedures performed by conformity assessment bodies under this Agreement prior to termination, unless a Regulatory Authority in the Party decides otherwise based on health, safety and environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex.

ARTICLE 22

FINAL PROVISIONS

1. The Sectoral Annexes referred to in Article 21(1), as well as any New Sectoral Annexes added pursuant to Article 21(2), shall form an integral part of this Agreement.
2. For a given product or sector, the provisions contained in the relevant Sectoral Annexes shall apply in the first place, and the provisions of this text in addition to those provisions. In the case of any inconsistency between the provisions of a Sectoral Annex and this text, the Sectoral Annex shall prevail, to the extent of that inconsistency.
3. This Agreement shall not affect the rights and obligations of the Parties under any other international agreement.
4. In the case of the Sectoral Annex on Medical Devices, the Parties shall review the status of such Annex at the end of three years from entry into force.

This Agreement and the Sectoral Annexes are drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish and Swedish languages, each text being equally authentic. In the event of inconsistencies of interpretation, the English text shall be determinative.

U.S. - EC MRA Telecommunication Equipment Annex

**SECTORAL ANNEX
FOR
TELECOMMUNICATION EQUIPMENT**

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition of Conformity Assessment between the United States and the European Community.

U.S. - EC MRA Telecommunication Equipment Annex

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

EC	U.S.
<p>Directive 98/13/EC of the European Parliament and of the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity, and interpretation thereof</p> <p>(The Parties recognize that the Handbook on the implementation of Directive 98/13/EC (ADLNB and ACTE approved), provides useful guidelines for the implementation of conformity assessment procedures falling under this Directive.);</p> <p>Commission Decisions (CTRs) established under Directive 98/13/EC;</p> <p>The EC Member States' legislation and regulations in respect of:</p> <ul style="list-style-type: none">(a) non-harmonized analogue connection to the public telecommunications network*;(b) non-harmonized radio transmitters for which there is a civilian equipment authorization requirement; <p>* The EC agrees to seek authority to include non-harmonized digital connections;</p> <p>For electrical safety, see Electrical Safety Sectoral Annex to the Agreement;</p> <p>For electromagnetic compatibility aspects, see Electromagnetic Compatibility (EMC) Sectoral Annex to the Agreement.</p>	<p>Communications Act of 1934, as amended by the Telecommunication Act of 1996, (Title 47 of the United States Code),</p> <p>the U.S. regulatory and administrative provisions in respect of telecommunication equipment, including 47 CFR Part 68, and FCC interpretation thereof;</p> <p>(The Parties recognize that the FCC Form 730 Application Guide provides useful guidelines for the implementation of conformity assessment procedures for telecommunication terminal equipment falling within these regulations.);</p> <p>The U.S. regulatory and administrative provisions in respect of all radio transmitters subject to an equipment authorization requirement. A non-exclusive list of FCC regulations are contained in Section II;</p> <p>For electrical safety, see Electrical Safety Sectoral Annex to the Agreement;</p> <p>For electromagnetic compatibility aspects, see Electromagnetic Compatibility (EMC) Sectoral Annex to the Agreement.</p>

U.S. - EC MRA Telecommunication Equipment Annex

SECTION II

SCOPE AND COVERAGE

1. This Sectoral Annex shall apply to equipment, interfaces, and services subject to Section I. In general terms the provisions of this Sectoral Annex shall apply to the following types of telecommunication terminal equipment, satellite terminal equipment, radio transmitters, and information technology equipment:
 - (a) equipment intended for connection to the public telecommunications network in order to send, process or receive information, whether the equipment is to be connected directly to the "termination" of the network or to inter-work with such a network, being connected directly or indirectly to the termination point. The system of connection may be wire, radio, optical or other electro-magnetic means;
 - (b) equipment capable of being connected to a public telecommunications network even if it is not its intended purpose, including information technology equipment having a communication port; and
 - (c) all radio transmitters subject to an equipment authorization procedure by either Party.
2. The following is a non-exclusive list of the equipment, interfaces, and services included within the scope of this Sectoral Annex:

U.S. - EC MRA Telecommunication Equipment Annex

SECTION II (continued)

SCOPE AND COVERAGE

EC	U.S.
<p>The following equipment categories are included:</p> <p>ISDN Basic Rate Access</p> <p>ISDN Primary Rate Access</p> <p>ISDN Telephony</p> <p>X21/V.24/V.35 Access</p> <p>X25 Access</p> <p>PSTN Non-Voice</p> <p>PSTN Voice Band (Analog)</p> <p>ONP Leased Line Terminal types:</p> <ul style="list-style-type: none"> -64 kbits/sec -2048 kbits/s unstructured -2048 kbits/s structured -34 Mbits/s access -140 Mbits/s access -2 wire analogue -4 wire analogue <p>Radio transmitters subject to an equipment authorization requirement, including:</p> <ul style="list-style-type: none"> -Short range devices, including low power devices such as cordless telephones/microphones; -Land mobile, including: <ul style="list-style-type: none"> - Private Mobile Radio (PMR/PAMR) - Mobile telecom - Paging systems - Terrestrial fixed - Satellite mobile - Satellite fixed - Broadcast - Radio determination 	<p>Equipment categories covered under 47 CFR Part 68, including:</p> <p>ISDN Basic Access</p> <p>ISDN Primary Rate Access</p> <p>Digital Service Access:</p> <ul style="list-style-type: none"> 2.4 kbps 3.2 kbps (2.4 kbps with Secondary Channel) 4.8 kbps 6.4 kbps (4.8 kbps with SC) 9.6 kbps 12.8 kbps (9.6 kbps with SC) 19.2 kbps 25.0 kbps (19.2 kbps with SC) 56.0 kbps 64.0 kbps (uses 72 kbps channel) 72.0 kbps (56.0 kbps with SC) 1.544 Mbps <p>2 wires analog tie trunks/ops</p> <p>4 wire analog tie trunks/ops</p> <p>PSTN Voice Band (Analog) Access</p> <p>Private Line (Analog) Access</p> <p>Radio transmitters subject to an equipment authorization requirement, including:</p> <ul style="list-style-type: none"> Commercial Mobile Radio (Part 20) Domestic Public Fixed (Part 21) Domestic Mobile (Part 22) Personal Communication Service (Part 24) Satellite Communications (Part 25) Broadcast (Part 73) Auxiliary Broadcast (Part 74) Cable Television Radio (Part 78) Maritime (Part 80) GMDSS (Part 80W) Private Land Mobile (Part 90) Private-Fixed Microwave (Part 94) Personal Radio Services (Part 95) IVDS (Part 95 F) Amateur Radio (Part 97) Radio Frequency Devices (Part 15) Fixed Microwave Services (Part 101)

Note: A list of acronyms and a glossary is contained in Appendix I to this Sectoral Annex.

SECTION III

CONFORMITY ASSESSMENT PROCEDURES
FOR TELECOMMUNICATION EQUIPMENT

1. Description of Mutual Recognition Obligations

In accordance with the provisions of the Agreement, the results of the conformity assessment procedures produced by a Party's conformity assessment bodies listed in Section V shall be recognized by the Regulatory Authorities of the other Party without any further conformity assessment of the products, pursuant to Section I.

2. Conformity Assessment Procedures

Taking into account the legislative, regulatory, and administrative provisions as identified in Section I, each Party recognizes that the conformity assessment bodies of the other Party, listed in Section V, are authorized to perform the following procedures with regard to the importing Party's technical requirements for telecommunication terminal equipment, satellite terminal equipment, radio transmitters or information technology equipment:

- (a) testing and issuing of test reports;
- (b) issuing certificates of conformity to the requirements of the laws and regulations applicable in the territories of the Parties for products covered under this Sectoral Annex; and
- (c) performing quality assurance certification pursuant to Directive 98/13/EC.

U.S. - EC MRA Telecommunication Equipment Annex

SECTION IV

AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

EC	U.S.
<p>Belgium Institut belge des services postaux et des télécommunications Belgisch instituut voor postdiensten en telecommunicatie</p> <p>Denmark: Telestyrelsen</p> <p>Germany: Bundesministerium für Wirtschaft</p> <p>Greece: Υπουργείο Μεταφορών και Επικοινωνιών Ministry of Transport and Communications</p> <p>Spain: Ministerio de Fomento</p> <p>France: Ministère de l'économie, des finances et de l'industrie</p> <p>Ireland: Department of Transport, Energy and Communications</p> <p>Italy: Ispettorato Generale TLC</p> <p>Luxembourg: Administration des Postes et Télécommunications</p> <p>Netherlands: De Minister van Verkeer en Waterstaat</p> <p>Austria: Bundesministerium für Wissenschaft und Verkehr</p> <p>Portugal: Instituto das Comunicações de Portugal</p> <p>Finland: Liikenneministeriö/Trafikministeriet Telehallintokeskus/Teleförvaltningscentralen</p> <p>Sweden: Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC)</p> <p>UK: Department of Trade and Industry</p>	<p>National Institute of Standards and Technology (NIST)</p> <p>Federal Communications Commission (FCC)</p>

U.S. - EC MRA Telecommunication Equipment Annex

SECTION V

CONFORMITY ASSESSMENT BODIES

EC access to US market	U.S. access to EC market
Conformity assessment bodies located in the EC shall be designated by the Authorities identified in Section IV following the procedures set out in Section VI of this Annex.	Conformity assessment bodies located in the U.S. shall be designated by the Authorities identified in Section IV following the procedures set out in Section VI of this Annex.
(to be provided by the EC)	(to be provided by the U.S.)

SECTION VI

DESIGNATING, LISTING, SUSPENDING, WITHDRAWING AND MONITORING
CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

EC access to U.S. market:	U.S. access to EC market:
<p>EC Authorities identified in Section IV shall designate conformity assessment bodies located in the EC in accordance with the U.S. legislative, regulatory, and administrative provisions identified in Section I that govern designation of conformity assessment bodies, based on compliance with the appropriate ISO/IEC Guides (e.g. Guide 22, 25, 28, 58, 61, 62, 65, etc.) or the comparable EN-45000 Series Standards.</p> <p>Procedures for designating, listing, suspending, withdrawing, and monitoring a conformity assessment body listed in Section V shall be undertaken pursuant to Articles 7, 8, 9 and 10 of the Agreement.</p>	<p>U.S. Authorities identified in Section IV shall designate conformity assessment bodies located in the U.S. in accordance with the EC legislative, regulatory, and administrative provisions identified in Section I that govern designation of conformity assessment bodies, based on compliance with the appropriate EN-45000 Series Standards or the comparable ISO/IEC Guides (e.g. Guide 22, 25, 28, 58, 61, 62, 65, etc.).</p> <p>Procedures for designating, listing, suspending, withdrawing, and monitoring a conformity assessment body listed in Section V shall be undertaken pursuant to Articles 7, 8, 9 and 10 of the Agreement.</p>

U.S. - EC MRA Telecommunication Equipment Annex

SECTION VII

ADDITIONAL PROVISIONS

1. SUB-CONTRACTING

- 1.1. Any sub-contracting by conformity assessment bodies shall be in accordance with the sub-contracting requirements of the other Party. Notwithstanding the use of sub-contracting, the final results of conformity assessment remain the full responsibility of the listed conformity assessment body. In the EC, these requirements are described in Council Decision 93/465/EEC.**
- 1.2. The conformity assessment bodies shall record and retain details of their investigation of the competence and compliance of their subcontractors and maintain a register of all sub-contracting. These details will be available to the other Party on request.**

U.S. - EC MRA Telecommunication Equipment Annex

2. POST-MARKET SURVEILLANCE, BORDER MEASURES AND INTERNAL MOVEMENT

- 2.1. For the purpose of post-market surveillance, the Parties may maintain any existing labelling and numbering requirements. The assignment of the numbers may take place in the territory of the exporting Party. The numbers will be allocated by the importing Party. Numbering and labelling systems shall not introduce additional requirements within the meaning of this Sectoral Annex.
- 2.2. Nothing in this Sectoral Annex shall prevent the Parties from removing products from the market that do not in fact conform to the requirements for approval.
- 2.3. The Parties agree that border inspections and checks of products which have been certified, labelled or marked as conforming with the importing Party's requirements specified in Section I shall be completed as expeditiously as possible. With regard to any inspections related to internal movement within their respective territories, the Parties agree that these shall be completed in no less a favourable manner than for like-domestic goods.

3. JOINT SECTORAL COMMITTEE

- 3.1. A combined Joint Sectoral Committee for this Sectoral Annex and the Electromagnetic Compatibility (EMC) Sectoral Annex is hereby established (the JSC). The JSC shall operate during the transitional period and after completion of the transitional arrangement. The JSC shall meet as appropriate to discuss technical, conformity assessment and technology issues relating to this Sectoral Annex and the EMC Sectoral Annexes. The JSC shall determine its own rules of procedure.
- 3.2. The JSC consists of representatives of the U.S. and the EC for telecommunications and EMC. JSC representatives may each invite manufacturers and other entities as deemed necessary. The representatives for the U.S. shall have one vote in the JSC. The representatives of the EC shall have one vote in the JSC. Decisions of

U.S. - EC MRA Telecommunication Equipment Annex

the JSC shall be made by unanimous consent. In the event of disagreement either the U.S. or EC representative may raise the matter in the Joint Committee.

3.3. The JSC may address any matter related to the effective functioning of this Sectoral Annex, including:

- (a) providing a forum for discussion of issues and resolving problems that may arise concerning the implementation of this Sectoral Annex;**
- (b) developing a mechanism for ensuring consistency of interpretations of legislation, regulations, standards, and conformity assessment procedures;**
- (c) advising the Parties on matters relating to this Sectoral Annex; and**
- (d) providing guidance and, if necessary, developing guidelines during the transitional period to facilitate the successful completion of the transitional period.**

4. CONTACT POINT

Each Party shall establish a contact point to provide answers to all reasonable inquiries from the other Party regarding procedures, regulations, and complaints under this Sectoral Annex.

5. REGULATORY CHANGES AND UPDATING THE SECTORAL ANNEX

In the event that there are changes to the legislative, regulatory, and administrative provisions referenced in Section I or the introduction of new legislative, regulatory, and administrative provisions affecting either Party's conformity assessment procedures under the Agreement, such changes shall take effect for the purpose of this Sectoral Annex at the same time they take effect domestically within the